

WE CLAIM

1. A medical apparatus comprising:
 - a needle having a proximal end, a distal end, and an inner lumen extending from said proximal end to said distal end;
 - 5 a stylet having a proximal end and a distal end, wherein said stylet is adapted to be inserted into and withdrawn from said inner lumen of said needle with at least a portion of said stylet adapted to plug said inner lumen of said needle when a cytology sample is cut; and
 - 10 a cytology collection device having a proximal end and a distal end, wherein said cytology collection device is adapted to be inserted into said inner lumen of said needle when said stylet is withdrawn from the inner lumen of said needle, with said distal end of said cytology collection device adapted to extend beyond the distal end of said needle in order to collect said cytology sample.
2. An apparatus according to claim 1, wherein said cytology collection device comprises an elongate member having a proximal end, a distal end, and a plurality of bristles.
 - 15 3. An apparatus according to claim 1, wherein said distal end of said cytology collection device terminates in one of a cap, ball tip, cone tip, bevel tip, and loop.
 4. An apparatus according to claim 3, wherein one of said cap, ball tip, cone tip, bevel tip, and loop is made of one or more of steel, metal, and solder.
 - 20 5. An apparatus according to claim 2, wherein said elongate member comprises a wire and said wire is twisted around said plurality of bristles.
 6. An apparatus according to claim 5, wherein said wire is made of one or more of steel, metal, and nitinol.
 - 25 7. An apparatus according to claim 2, wherein the distal end of the elongate member is adapted to be retracted within the inner lumen of said needle after collecting said cytology sample.
 8. An apparatus according to claim 1, wherein said needle is made of one or more of steel, and metal.
- 30 9. An apparatus according to claim 2, wherein said plurality of bristles is made of one or more of nylon, brass, stainless steel, metal, carbon, and polymer.

10. An apparatus according to claim 1, wherein said needle is adapted to provide suction.

11. An apparatus according to claim 1, further comprising a handle which is adapted to provide axial movement of said cytology collection device and said needle.

5 12. An apparatus according to claim 11, wherein said handle comprises:
an inner handle member having a proximal end and a distal end;
a first outer handle member slideably disposed on the inner handle member;
and

10 an elongate sheath attached to the inner handle member and axially extending beyond the distal end of the inner handle member, the sheath defining a sheath lumen, wherein said needle is attached to the first outer handle member and disposed in the sheath lumen.

15 13. An apparatus according to claim 11, wherein said handle comprises:
an inner handle member having proximal and distal ends and defining a handle lumen;

16 a first outer handle member slideably disposed on the proximal end of the inner handle member;
a second outer handle member slideably disposed on the distal end of the inner handle member;

20 an elongate sheath attached to the inner handle member and axially extending beyond the distal end of the inner handle member, the sheath defining a sheath lumen, wherein said needle is attached to the first outer handle member, the needle extending through the handle lumen and into the sheath lumen; and

25 a cap slideably disposed at the proximal end of the first outer handle member, said cap connected to the cytology collection device.

14. An apparatus according to claim 13, further comprising an endoscope defining a working lumen, wherein said elongate sheath axially extends into the working lumen of the endoscope.

30 15. An apparatus according to claim 11, wherein said handle comprises one of a finger-loop handle, a pin-vice handle, and a half-finger loop handle.

16. An apparatus according to claim 1, further comprising an endoscope containing a transducer which is adapted to emit ultrasound waves to determine a position of said cytology collection device within a mammalian body using said ultrasound waves.

5 17. An apparatus according to claim 16, wherein said cytology collection device comprises a dimpled wire having a proximal end, a distal end, and a plurality of bristles, wherein said transducer is adapted to emit ultrasound waves capable of reflecting off said dimpled wire.

10 18. An apparatus according to claim 16, wherein said cytology collection device comprises an elongate member having a proximal end, a distal end, and a plurality of bristles, wherein said transducer is adapted to emit ultrasound waves capable of reflecting off said plurality of bristles.

15 19. An apparatus according to claim 18, wherein said plurality of bristles is made of one or more of nylon, brass, stainless steel, metal, carbon, and polymer.

20. An apparatus according to claim 1, wherein said stylet is a solid rod.

21. An apparatus according to claim 1, wherein said stylet is made of one or more of steel, metal, and nitinol.

20 22. An apparatus according to claim 1, wherein said cytology collection device comprises a balloon adapted to fit within said inner lumen of said needle when deflated and adapted to inflate when outside of said inner lumen of said needle in order to collect said cytology sample.

23. An apparatus according to claim 22, wherein an outer surface of said balloon is rough.

25 24. An apparatus according to claim 22, wherein said balloon is made of one or more of polymer, silicone, and polyethylene terephthalate.

25 25. An apparatus according to claim 1, further comprising a marker near said proximal end of said cytology collection device which is adapted to indicate when said distal end of said cytology collection device has been extended beyond the distal end of said needle.

30 26. An apparatus according to claim 1, wherein said distal end of said stylet is adapted to cut said cytology sample.

27. An apparatus according to claim 26, wherein said distal end of said stylet is sharp.

28. An apparatus according to claim 26, wherein said distal end of said stylet is adapted to extend beyond the distal end of said needle.

5 29. An apparatus according to claim 1, wherein an outer surface of said stylet has a first diameter and an inner surface of said needle has a second diameter slightly larger than said first diameter, wherein said outer surface of said stylet is adapted to contact said inner surface of said needle to plug said inner lumen of said needle while said cytology sample is cut.

10 30. An apparatus according to claim 1, wherein said cytology collection device comprises a wire mesh device.

31. A medical apparatus for collecting a cytology sample from a mammalian body comprising:

15 an endoscope containing a transducer, said endoscope defining a working lumen;

a member having a proximal end, a distal end, and an inner lumen, wherein said member extends into the working lumen of said endoscope; and

20 a cytology collection device having a proximal end, and a distal end for cytology collection, wherein said cytology collection device is adapted to be inserted into said inner lumen of said member, with said distal end of said cytology collection device adapted to extend beyond the distal end of said member in order to collect said cytology sample, wherein said transducer is adapted to emit ultrasound waves to determine a position of said cytology collection device within said mammalian body using said ultrasound waves.

25 32. An apparatus according to claim 31, wherein said cytology collection device comprises an elongate member having a proximal end, a distal end, and a plurality of bristles.

30 33. An apparatus according to claim 32, wherein said elongate member comprises a dimpled wire and said transducer is adapted to emit ultrasound waves capable of reflecting off said dimpled wire.

34. An apparatus according to claim 32, wherein said transducer is adapted to emit ultrasound waves capable of reflecting off said plurality of bristles.
35. An apparatus according to claim 34, wherein said plurality of bristles is made of one or more of nylon, brass, stainless steel, metal, carbon, and polymer.
- 5 36. An apparatus according to claim 31, wherein said member is a needle.
37. An apparatus according to claim 31, wherein said distal end of said cytology collection device terminates in one of a cap, ball tip, cone tip, bevel tip, and loop.
- 10 38. An apparatus according to claim 37, wherein one of said cap, ball tip, cone tip, bevel tip, and loop is made of one or more of steel, metal, and solder.
39. An apparatus according to claim 32, wherein said elongate member comprises a wire and said wire is twisted around said plurality of bristles.
40. An apparatus according to claim 39, wherein said wire is made of one or more of steel, metal, and nitinol.
- 15 41. An apparatus according to claim 32, wherein the distal end of the elongate member is adapted to be retracted within the inner lumen of said member after collecting said cytology sample.
42. An apparatus according to claim 31, wherein said member is made of one or more of steel, and metal.
- 20 43. An apparatus according to claim 31, wherein said member is adapted to provide suction.
44. An apparatus according to claim 31, further comprising a handle which is adapted to provide axial movement of said cytology collection device and said member.
- 25 45. An apparatus according to claim 44, wherein said handle comprises:
an inner handle member having a proximal end and a distal end;
a first outer handle member slideably disposed on the inner handle member;
and
an elongate sheath attached to the inner handle member and axially extending beyond the distal end of the inner handle member, the sheath defining a sheath

lumen, wherein said member is attached to the first outer handle member and disposed in the sheath lumen.

46. An apparatus according to claim 44, wherein said handle comprises:
an inner handle member having proximal and distal ends and defining a handle
5 lumen;
a first outer handle member slideably disposed on the proximal end of the inner handle member;
a second outer handle member slideably disposed on the distal end of the inner handle member;
10 an elongate sheath attached to the inner handle member and axially extending beyond the distal end of the inner handle member, the sheath defining a sheath lumen, wherein said member is attached to the first outer handle member, the member extending through the handle lumen and into the sheath lumen; and
a cap slideably disposed at the proximal end of the first outer handle member,
15 said cap connected to the cytology collection device.
47. An apparatus according to claim 46, wherein said elongate sheath axially extends into the working lumen of the endoscope.
48. An apparatus according to claim 44, wherein said handle comprises one of a finger-loop handle, a pin-vice handle, and a half-finger loop handle.
- 20 49. An apparatus according to claim 31, wherein said cytology collection device comprises a balloon adapted to fit within said inner lumen of said member when deflated and adapted to inflate when outside of said inner lumen of said member in order to collect said cytology sample.
50. An apparatus according to claim 49, wherein an outer surface of said
25 balloon is rough.
51. An apparatus according to claim 49, wherein said balloon is made of one or more of polymer, silicone, and polyethylene terephthalate.
52. An apparatus according to claim 31, further comprising a marker near said proximal end of said cytology collection device which is adapted to indicate when
30 said distal end of said cytology collection device has been extended beyond the distal end of said member.

53. A method for collecting a cytology sample from a mammalian body comprising:

5 providing an apparatus comprising: a needle having a proximal end, a distal end, and an inner lumen extending from said proximal end to said distal end; a stylet having a proximal end and a distal end; and a cytology collection device having a proximal end and a distal end for cytology collection;

inserting said stylet into said inner lumen of said needle, wherein at least a portion of said stylet plugs said inner lumen of said needle;

10 cutting an area within said mammalian body;

withdrawing said stylet from said inner lumen of said needle;

15 inserting said cytology collection device into said inner lumen of said needle so that said distal end of said cytology collection device extends beyond the distal end of said needle;

collecting said cytology sample from said mammalian body using said cytology collection device; and

15 retracts said distal end of said cytology collection device into said inner lumen of said needle.

54. A method according to claim 53, wherein said cytology collection device comprises an elongate member having a proximal end, a distal end, and a plurality of bristles.

55. A method according to claim 53, wherein said distal end of said cytology collection device terminates in one of a cap, ball tip, cone tip, bevel tip, and loop.

56. A method according to claim 55, wherein one of said cap, ball tip, cone tip, bevel tip, and loop is made of one or more of steel, metal, and solder.

25 57. A method according to claim 54, wherein said elongate member comprises a wire and said wire is twisted around said plurality of bristles.

58. A method according to claim 57, wherein said wire is made of one or more of steel, metal, and nitinol.

30 59. A method according to claim 53, wherein said needle is made of one or more of steel, and metal.

60. A method according to claim 54, wherein said plurality of bristles is made of one or more of nylon, brass, stainless steel, metal, carbon, and polymer.

61. A method according to claim 53, further providing the step of providing suction through said needle.

5 62. A method according to claim 53, wherein the provided apparatus further comprises a handle which is adapted to provide at various points in time axial movement of said stylet, axial movement of said cytology collection device, and axial movement of said needle.

10 63. A method according to claim 62, wherein said handle comprises:

an inner handle member having a proximal end and a distal end;
a first outer handle member slideably disposed on the inner handle member;
and

15 an elongate sheath attached to the inner handle member and axially extending beyond the distal end of the inner handle member, the sheath defining a sheath lumen, wherein said needle is attached to the first outer handle member and disposed in the sheath lumen.

64. A method according to claim 62, wherein said handle comprises:

an inner handle member having proximal and distal ends and defining a handle lumen;

20 a first outer handle member slideably disposed on the proximal end of the inner handle member;

 a second outer handle member slideably disposed on the distal end of the inner handle member;

25 an elongate sheath attached to the inner handle member and axially extending beyond the distal end of the inner handle member, the sheath defining a sheath lumen, wherein said needle is attached to the first outer handle member, the needle extending through the handle lumen and into the sheath lumen; and

 a cap slideably disposed at the proximal end of the first outer handle member, said cap connected to said stylet.

30 65. A method according to claim 64, wherein said cap is attached to the proximal end of said stylet, and the steps of inserting said stylet into the inner

lumen of the needle, cutting an area within the body, and withdrawing the stylet from the inner lumen of the needle are all achieved by slideably moving said cap axially.

66. A method according to claim 62, wherein said handle comprises:

5 an inner handle member having proximal and distal ends and defining a handle lumen;

a first outer handle member slideably disposed on the proximal end of the inner handle member;

10 a second outer handle member slideably disposed on the distal end of the inner handle member;

an elongate sheath attached to the inner handle member and axially extending beyond the distal end of the inner handle member, the sheath defining a sheath lumen, wherein said needle is attached to the first outer handle member, the needle extending through the handle lumen and into the sheath lumen; and

15 a cap slideably disposed at the proximal end of the first outer handle member, said cap connected to said cytology collection device.

67. A method according to claim 66, wherein said cap is attached to the proximal end of said cytology collection device, and the steps of inserting said cytology collection device into the inner lumen of the needle, collecting the cytology sample from the body, and retracting the cytology collection device into the inner lumen of said needle are all achieved by slideably moving said cap axially.

25 68. A method according to claim 66, wherein the provided apparatus further comprises an endoscope defining a working lumen, wherein said elongate sheath axially extends into the working lumen of the endoscope.

69. A method according to claim 62, wherein said handle comprises one of a finger-loop handle, a pin-vice handle, and a half-finger loop handle.

30 70. A method according to claim 53, wherein the provided apparatus further comprises an endoscope containing a transducer adapted to emit ultrasound waves, and the method further comprises the additional step of determining a position of

5 said cytology collection device within said mammalian body through ultrasound waves emitted by said transducer.

71. A method according to claim 70, wherein said cytology collection device comprises a dimpled wire having a proximal end, a distal end, and a plurality of bristles, wherein said transducer is adapted to emit ultrasound waves capable of reflecting off said dimpled wire.

10 72. A method according to claim 70, wherein said cytology collection device comprises an elongate member having a proximal end, a distal end, and a plurality of bristles, wherein said transducer is adapted to emit ultrasound waves capable of reflecting off said plurality of bristles.

15 73. A method according to claim 72, wherein said plurality of bristles is made of one or more of nylon, brass, stainless steel, metal, carbon, and polymer.

74. A method according to claim 53, wherein said stylet is a solid rod.

20 75. A method according to claim 53, wherein said stylet is made of one or more of steel, metal, and nitinol.

25 76. A method according to claim 53, wherein said cytology collection device comprises a balloon adapted to fit within said inner lumen of said needle when deflated and adapted to inflate when outside of said inner lumen of said needle in order to collect said cytology sample.

77. A method according to claim 76, wherein an outer surface of said balloon is rough.

78. A method according to claim 76, wherein said balloon is made of one or more of polymer, silicone, and polyethylene terephthalate.

25 79. A method according to claim 53, further comprising a marker near said proximal end of said cytology collection device which is adapted to indicate when said distal end of said cytology collection device has been extended beyond the distal end of said needle.

80. A method according to claim 53, wherein said distal end of said stylet is used to cut an area within said mammalian body.

30 81. A method according to claim 80, wherein said distal end of said stylet is sharp.

82. A method according to claim 80, wherein when said stylet is inserted into said inner lumen of said needle the distal end of said stylet is extended beyond the distal end of said needle.

5 83. A method according to claim 53, wherein an outer surface of said stylet has a first diameter and an inner surface of said needle has a second diameter slightly larger than said first diameter, wherein said outer surface of said stylet is adapted to contact said inner surface of said needle to plug said inner lumen of said needle while said area within said body is cut.

10 84. A method according to claim 53, wherein said cytology collection device comprises a wire mesh device.

 85. A method for collecting a cytology sample from a mammalian body comprising:

15 providing an apparatus comprising: an endoscope, said endoscope defining a working lumen and containing a transducer; a member having a proximal end, a distal end, and an inner lumen, wherein said member extends into the working lumen of said endoscope; and a cytology collection device having a proximal end, and a distal end for cytology collection, wherein said cytology collection device extends into said inner lumen of said member;

20 inserting said working lumen of said endoscope into said mammalian body;

 extending said distal end of said cytology collection device beyond the distal end of said member;

 emitting ultrasound waves from said transducer of said endoscope;

 reflecting said ultrasound waves off said cytology collection device;

25 receiving said reflected ultrasound waves using said transducer of said endoscope; and

 determining a position of said cytology collection device within said mammalian body.

30 86. A method according to claim 85, wherein said cytology collection device comprises an elongate member having a proximal end, a distal end, and a plurality of bristles.

87. A method according to claim 85, wherein said distal end of said cytology collection device terminates in one of a cap, ball tip, cone tip, bevel tip, and loop.

88. A method according to claim 87, wherein one of said cap, ball tip, cone tip, bevel tip, and loop is made of one or more of steel, metal, and solder.

5 89. A method according to claim 86, wherein said elongate member comprises a wire, wherein said wire is twisted around said plurality of bristles.

90. A method according to claim 89, wherein said wire is made of one or more of steel, metal, and nitinol.

10 91. A method according to claim 85, wherein said member is made of one or more of steel, and metal.

92. A method according to claim 86, wherein said plurality of bristles is made of one or more of nylon, brass, stainless steel, metal, carbon, and polymer.

93. A method according to claim 85, further providing the step of providing suction through said member.

15 94. A method according to claim 85, wherein said member is a needle.

95. A method according to claim 85, wherein the provided apparatus further comprises a handle which is adapted to provide at various points in time axial movement of said member, and axial movement of said cytology collection device.

20 96. A method according to claim 95, wherein said handle comprises:

an inner handle member having a proximal end and a distal end;

a first outer handle member slideably disposed on the inner handle member; and

25 an elongate sheath attached to the inner handle member and axially extending beyond the distal end of the inner handle member, the sheath defining a sheath lumen, wherein said member is attached to the first outer handle member and disposed in the sheath lumen.

97. A method according to claim 95, wherein said handle comprises:

an inner handle member having proximal and distal ends and defining a handle lumen;

- a first outer handle member slideably disposed on the proximal end of the inner handle member;
- a second outer handle member slideably disposed on the distal end of the inner handle member;
- 5 an elongate sheath attached to the inner handle member and axially extending beyond the distal end of the inner handle member, the sheath defining a sheath lumen, wherein said member is attached to the first outer handle member, the member extending through the handle lumen and into the sheath lumen; and
- 10 a cap slideably disposed at the proximal end of the first outer handle member, said cap connected to said cytology collection device.
98. A method according to claim 97, wherein said cap is attached to the proximal end of said cytology collection device, and the step of extending said distal end of said cytology collection device beyond the distal end of the member is accomplished by slideably moving said cap axially.
- 15 99. A method according to claim 97, wherein said elongate sheath axially extends into the working lumen of the endoscope.
100. A method according to claim 95, wherein said handle comprises one of a finger-loop handle, a pin-vice handle, and a half-finger loop handle.
- 20 101. A method according to claim 85, wherein said cytology collection device comprises a dimpled wire having a proximal end, a distal end, and a plurality of bristles, wherein said transducer is adapted to emit ultrasound waves which are capable of reflecting off said dimpled wire.
- 25 102. A method according to claim 85, wherein said cytology collection device comprises an elongate member having a proximal end, a distal end, and a plurality of bristles, wherein said transducer is adapted to emit ultrasound waves which are capable of reflecting off said plurality of bristles.
103. A method according to claim 102, wherein said plurality of bristles is made of one or more of nylon, brass, stainless steel, metal, carbon, and polymer.
- 30 104. A method according to claim 85, wherein said cytology collection device comprises a balloon adapted to fit within said inner lumen of said member when

deflated and adapted to inflate when outside of said inner lumen of said member in order to collect said cytology sample.

105. A method according to claim 104, wherein an outer surface of said balloon is rough.

5 106. A method according to claim 104, wherein said balloon is made of one or more of polymer, silicone, and polyethylene terephthalate.

107. A method according to claim 85, further comprising a marker near said proximal end of said cytology collection device which is adapted to indicate when said distal end of said cytology collection device has been extended beyond the distal end of said member.